



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 04, 2016

Mashiur Bhuiyan
Regulatory Affairs
Micrylium Laboratories Inc.
5000-M Dufferin Street
North York, Toronto, Canada M3H 5T5

Subject: Notification per PRN 98-10 – Updating the label to add company information
And Slogan and other label updates.
Product Name: BioSURF
EPA Registration Number: 70467-3
Application Date: July 04, 2016
Decision Number: 519343

Dear Mr. Bhuiyan,

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Lorena Rivas at 703-305-5027 or via email at rivas.lorena@epa.gov.

Sincerely,

A handwritten signature in blue ink, consisting of several overlapping, fluid strokes that are difficult to decipher as specific text.

for

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Notification Label



Net Contents

16.9 fl oz
500 ml

EPA Registration Number 70467-3
EPA Establishment 070467-CAN-001

Hospital Hard Surface Disinfectant

BioSURE is a ready to use hard surface disinfectant
for nonporous surfaces • One Step

<u>Active Ingredients</u>	
Ethanol	70.5%
Chlorhexidine Gluconate	0.2%
<u>Other Ingredients</u>	29.3%
Total	100.0%

Tuberculocidal - Canine Parvovirucidal
Pseudomonacidal

CAUTION

READ PRECAUTIONS ON BACK PANEL • KEEP OUT OF THE REACH OF CHILDREN

Less Waste • Less Space

Directions for use

- Aldehyde
- NPE
- Phenol
- Free



BioSURF™ is a ready to use environmental hard surface disinfectant for nonporous surfaces. It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

BioSURF kills Tuberculosis (*Mycobacterium bovis* BCG) and is Virucidal (*Canine parvovirus* CPV-265) in one minute in the presence of 5% bioburden. **BioSURF** kills *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* (formerly choleraesuis) in 20 seconds in the presence of 10% bioburden. **BioSURF** kills *Trichophyton mentagrophytes* in 10 seconds in the presence of 10% bioburden. To effectively kill bacteria, fungi and inactivate canine parvovirus use **BioSURF**. Remove trigger from 24 fl oz spray bottle. Cut this 16.9 fl oz refill pouch along the dotted line with scissors. Use a clean funnel to fill or refill bottle. Replace the trigger and rinse funnel. **BioSURF** is to be used on countertops and metal surfaces. May be used on wheelchairs, metal bed frames and exteriors of toilets. Spray all areas with a light mist. Maintain wetness for one minute to kill *Mycobacterium bovis* BCG and *Canine parvovirus* CPV-265. Maintain wetness for 20 seconds to kill bacteria and 10 seconds to kill fungi, then wipe with disposable paper towels or "Le Cloth™" towelettes.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.



www.micrylium.com
3309A Filmore • 5000M Dufferin
San Francisco, CA 94123 • Toronto, Canada M3H5T5

Developed with Conscience • Manufactured with Integrity • Tested with Sincerity • Presented with Care

Biodegradable OECD Test 301D

Precautionary Statements Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat or open flame. Keep out of the reach of children.

DO NOT use on alcohol sensitive materials such as hot plastic casings, acrylic paint, styrene or disposable plastic items.

Do not apply this product in or on electrical equipment due to the possibility of shock hazard.

FIRST AID: IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-489-8868 for emergency medical treatment information.

STORAGE & DISPOSAL: Do not contaminate water, food or feed by storage or disposal. **PESTICIDE STORAGE:** Do not store near open flame, at elevated temperature or in intense light. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or, by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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